



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

QM32/0910

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APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/372,966	08/12/99	037	TRUONG, K	3731 09/10/01
First Named Applicant	KIKUCHI, 35 USC 154(b) term ext. = 0 Days.			

TITLE OF INVENTION      INSERTION DEVICE FOR A DEFORMABLE INTRAOCULAR LENS

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
3	B-3425-DIV-6	606-107.000	L81	UTILITY	YES \$620.00	12/10/01

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

**I. Review the SMALL ENTITY status shown above.**

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

**II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.**

**III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.**

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

PATENT AND TRADEMARK OFFICE COPY

# Notice of Allowability

Application No.

09/372,966

Applicant(s)

Kikuchi et al.

Examiner

Kevin Truong

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to CPA 12/22/01 and Amendt. 6/25/01.
2. ☒ The allowed claim(s) is/are 4-7, 19-31, and 34-53.
3. ☐ The drawings filed on \_\_\_\_\_ are acceptable as formal drawings.
4. ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☒ Certified copies of the priority documents have been received in Application No. 09/032,211.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \*Certified copies not received: \_\_\_\_\_

5. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE FOR SUBMITTING NEW FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION.** This three-month period for complying with the REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL is extendable under 37 CFR 1.136(a).

6. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7. ☒ Applicant MUST submit NEW FORMAL DRAWINGS  
(a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☒ to Paper No. 4.  
(b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the examiner.  
(c) ☐ including changes required by the attached Examiner's Amendment/Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

8. ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

## Attachment(s)

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____    |
| 5 <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449), Paper No(s). _____          | 6 <input type="checkbox"/> Examiner's Amendment/Comment                    |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
| 9 <input type="checkbox"/> Other   |  |

KEVIN TRUONG  
PATENT EXAMINER  
ART UNIT 3731

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***Specification***

1. The disclosure is objected to because of the following informalities: In page 11, line 19, "line F-F in fig. 9" should be --line F-F in fig. 10--.
2. Claims 10, 11, and 13-16 are objected to because of the following informalities: "said hinge portions" in claim 10, 11, and 13-15, line 3, and in claim 16, line 3-4, should be -- said hinge portion--.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 10, line 4, and in claim 13, line 4, "said body" lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

An anticipation under 35 U.S.C. 102(b) or 102(e) is established when a single prior art reference discloses, either expressly or under principles of inherency, each and every element of a claimed invention. See RCA Corp. v. Applied Digital Data Systems, Inc., 730 F.2d 1440, 221 USPQ 385 (Fed. Cir. 1984).

It is well settled that the law of anticipation does not require that the reference teach what appellant is teaching or has disclosed, but only that the claims on appeal "read on" something disclosed in the reference, i.e., all limitations of the claims are found in the reference. See Kalman v. Kimberly Clark Corp., 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1083). Moreover, it is not necessary for the applied reference to expressly disclose or describe a particular element or limitation of a rejected claim word for word as in the rejected claim so long as the reference inherently discloses that element or limitation. See, for example, Standard Havens Products Inc. v. Gencor Industries Inc., 953 F.2d 1360, 21 USPQ2d 1321 (Fed. Cir. 1991).

6. Claims 4, 5, 7, 10, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakajima et al. (5,496,328).

In regard to claims 4 and 7, Nakajima et al. disclose, in figure 1, an insertion device for inserting into the eye a deformable intraocular lens 1 having an optical part 2 which is made of and elastic material and which has predetermined memory characteristics, and a supporting portion 3 which is made of a different from that of the optical part, as disclosed in fig. 4 and col.

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3, lines 32-37. Said insertion device comprises an enclosing member 24, which has a hinge portion 29, for holding said lens in advance, and a holder 37 for closing said enclosing member and maintaining the closed state.

In regard to claim 5, said deformable intraocular lens has a peripheral edge portion of the lens is an outer circumferential edge of the optical portion of the lens, as seen in figure 4.

In regard to claim 10, said enclosing member having said hinge portion and said holder are integrally build in a body of the insertion device, as seen in figure 2.

In regard to claim 14 and 15, said enclosing member having said hinge portion is transparent , as disclosed in column 6, lines 47-61, and said holder has an opening 23 serving as an observation window, as seen in figure 1.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one of ordinary skill in the art would be motivated to make the proposed combination of primary and secondary references. In re Nomiya, 184 USPQ 607

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(CCPA) 1975. However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. In re Bozek, 163 USPQ 545 (CCPA) 1969.

8. Claims 6, 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakajima et al. in view of Eagles et al. (5,616,148). Nakajima et al. disclose the invention substantially as claimed except they do not disclose the enclosing member is separated from a body of the insertion device, or the holder is an independent part, or the enclosing member and the holder are integrated together and are separated from the body. Eagles et al. teach, in column 4, lines 9-42, the three components, an enclosing member (lens cartridge), a holder (lens cartridge receiver), and a body (nozzle portion), could be separated or connected together when assembled in various manners. It would have been an obvious matter of design choice for the connection some or all of the said components for a desired assembling or a purposed separating of a insertion device for a deformable intraocular lens..

9. Claims 9, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakajima et al. in view of Eagles et al.. Nakajima et al. disclose the invention substantially as claim except they do not disclose the enclosing member comprising grooves on the inner surface having converging portions formed at front and rear sides of said grooves. Eagles et al. teach, in figure 11, grooves 22e on inner surface of an enclosing member having converging portions

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which are formed at front and rear sides of said groove for receiving and holding a deformable intraocular lens.

Therefore, it would have obvious to one having ordinary skill in the art at the same time the invention was made, in view of Eagles et al., to modify the insertion device for a deformable intraocular lens of Nakajima et al. having grooves for receive and holding said lens which has converging portions formed at front and rear sides of said grooves in order to stabilize the position of said lens on the enclosing member.

*Allowable Subject Matter*

10. Claims 1-3 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter: Claims 1-3 are allowed because the prior art of record fails to disclose or suggest an enclosing member for receiving and holding a deformable intraocular lens of a lens insertion device comprising a plurality of hinge portions.

12. Claims 8 and 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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*Conclusion*

13.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lien Ngo whose telephone number is (703) 305-0294. The examiner can normally be reached Monday through Friday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful. The examiner's supervisor, Michael Buiz, can be reached at (703)308-0871. The Group FAX number is (703) 305-3590.

Any inquiry of a general nature or relating to the status of the application should be directed to the Group receptionist at (703) 308-0858.

Lien Ngo

June 7, 2000